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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,698

Applicant(s)

POPE ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-17 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-17 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' preliminary amendment B and response to non-final action, received 9/3/2003, paper #10 is acknowledged. Claims 1, 3, 5-8, 12, 14, 16, 17, 20, 22-25 have been amended. Claims 9-10 and 18-19 have been canceled. New claims 26-27 have been added. Specification pages 6, 11 and 12 have been amended.

2. Currently claims 1-8, 11-17 and 20-27 are pending and under consideration.

Rejections Moot

3. Rejection of claims 18-19 under 35 U.S.C. 112, first paragraph made in paragraph 5 of the office action mailed 6/17/2003, paper # 8 is moot in view of cancellation of the claims.

4. Rejection of claim 9 under 35 U.S.C. 102 (b) made in paragraph 12 of the office action mailed 6/17/2003, paper # 8 is moot in view of cancellation of the claims.

5. Rejection of claims 9 and 10 under 35 U.S.C. 103 (a) made in paragraph 16 of the office action mailed 6/17/2003, paper # 8 is moot in view of cancellation of the claims.

Rejections Withdrawn

6. Rejection of claims 12-17, 20-21 and 25 under 35 U.S.C. 112, first paragraph made in paragraph 5 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

7. Rejection of claim 16 under 35 U.S.C. 112, first paragraph made in paragraph 6 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

8. Rejection of claims 2, 4, 11 and 13 under 35 U.S.C. 112, second paragraph made in paragraph 8 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' arguments.

9. Rejection of claims 1-8, 11 and 22 are rejected under 35 U.S.C. 102(b) made in paragraph

Art Unit: 1645

10 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

10. Rejection of claims 1-8, 11 and 22 are rejected under 35 U.S.C. 102(b) made in paragraph 11 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

11. Rejection of claims 1-2, 4 and 9 are rejected under 35 U.S.C. 102(b) made in paragraph 12 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

12. Rejection of claims 12-17 and 20-21 are rejected under 35 U.S.C. 102(b) made in paragraph 13 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

13. Rejection of claims 12-17 and 20-21 are rejected under 35 U.S.C. 102(b) made in paragraph 14 of the office action mailed 6/17/2003, paper # 8 is withdrawn in view of applicants' amendment.

Rejections Maintained

14. Rejection of claims 3, 5 - 8, 14, 16-17 and 22-25 under 35 U.S.C. 112, second paragraph made in paragraph 8 of the office action mailed 6/17/2003, paper # 8 is maintained.

The rejection was as stated below:

The terms "approximately" and "between approximately" in claims 3, 5- 8, 14, 16-17 and 22-25 are relative terms which render the claim indefinite. The terms are not defined by the

Art Unit: 1645

claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants have amended the claims and have replaced the term “approximately” with the term “about” in those claims. The replacement of the term does not overcome the rejection. Applicants argue that the Federal Circuit holds that the term about is not indefinite and present a copy of a case directed to a method of fracturing subterranean formulation to stimulate oil and gas wells as Exhibit A.

It is the examiner’s position that in instant case the term about is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The courts held the claims reciting “about” were indefinite where there is close prior art and there is nothing in the specification, and prosecution history to provide any indication as what range or specific activity is covered by the term about. (*Amgen, Inc. v. Chugai Pharmaceutical Co.*)

15. Rejection of claims 1 and 22-24 under 35 U.S.C. 103(a) made in paragraph 16 of the office action mailed 6/17/2003, paper # 8 is maintained.

The rejection was as stated below:

Claims 1 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabusaki, K. K. (US 4,738,932), and further in view of Avanti Polar Lipids product numbers 710332 and 850457.

The claims are drawn to an antigen composition comprising synthetic cardiolipin, synthetic lecithin, cholesterol and ethanol.

Art Unit: 1645

Yabusaki, K. K. discloses an antigen composition comprising synthetic cardiolipin, synthetic lecithin, cholesterol and ethanol (see claim 7). Yabusaki teaches a composition wherein the concentration of cardiolipin is 0.03 %, concentration of cholesterol is 0.9 %, and concentration of lecithin is approximately 0.21 % (see claim 7, column 3, lines 10-25 and column 4, lines 61-65). Yabusaki does not teach tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine. However, these products have been known in the art and are commercially available from Avanti Polar Lipids Inc. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the commercially available pure synthetic cardiolipin and lecithin powders having product numbers 710332 and 850457 to obtain the claimed composition.

Applicants' arguments filed September 3, 2003 have been fully considered but they are not persuasive.

Applicants argue " Given the number of possible synthetic cardiolipins and lecithins that have been combined, there was no *a priori* reason at time the invention was made to combine tetramyristol cardiolipin and 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine until applicants explained the significans of the combination."

It is the examiner's position that these synthetic cardiolipins and lecithins have been commercially available and the applicants have not provided a persuasive reason why one of ordinary skill in the art at the time the invention was made would not use the commercially available pure synthetic cardiolipin and lecithin powders having

Art Unit: 1645

product numbers 710332 and 850457 from the list of products offered by Avanti

Polar Lipids.

16. Rejection of claims 12 and 25 under 35 U.S.C. 103(a) made in paragraph 17 of the office action mailed 6/17/2003, paper # 8 is maintained.

The rejection was as stated below:

Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabusaki, K. K. (US 4,738,932), and further in view of Avanti Polar Lipids product numbers 710332 and 850457.

The claims are drawn to a method for detecting the presence of *Trepanoma palidum* in a human comprising combining a biological sample from the human with a composition comprising synthetic cardiolipin and synthetic lecithin and detecting an immunocomplex formed between an antibody in the biological sample and the composition.

Yabusaki, K. K. discloses a method for detecting the presence of *Trepanoma palidum* in a human comprising combining a biological sample from the human with a composition comprising synthetic cardiolipin and synthetic lecithin and detecting an immunocomplex formed between an antibody in the biological sample and the composition (see claim 14 and column 2, lines 36-39). Yabusaki teaches that the immunocomplex is detected using agglutination test (see abstract). Yabusaki teaches a composition wherein the concentration of cardiolipin is 0.03 %, concentration of cholesterol is 0.9 %, and concentration of lecithin is approximately 0.21 % (see claim 7, column 3, lines 10-25 and column 4, lines 61-65). Yabusaki does not teach

Art Unit: 1645

tetramyristoyl cardiolpin and 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine.

However, these products have been known in the art and are commercially available from Avanti Polar Lipids Inc. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the commercially available pure synthetic cardiolipin and lecithin powders having product numbers 710332 and 850457 to obtain the claimed method.

Applicants' arguments filed September 3, 2003 have been fully considered but they are not persuasive.

Applicants argue " Given the number of possible synthetic cardiolipins and lecithins that have been combined, there was no *a priori* reason at time the invention was made to combine tetramyristol cardiolipin and 1-palmitoyl-2-oleoyl-sn-glycero-3 phosphocholine until applicants explained the significans of the combination."

It is the examiner's position that these synthetic cardiolipins and lecithins have been commercially available and the applicants have not provided a persuasive reason why one of ordinary skill in the art at the time the invention was made would not use the commercially available pure synthetic cardiolipin and lecithin powders having product numbers 710332 and 850457 from the list of products offered by Avanti Polar Lipids.

New Rejections

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 1645

18. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claim 27 is a relative term, which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

19. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabusaki, K. K. (US 4,738,932), and further in view of Avanti Polar Lipids product numbers 710332 and 850457.

The claims are drawn to an antigen composition comprising synthetic cardiolipin, synthetic lecithin, cholesterol and ethanol.

Yabusaki, K. K. discloses an antigen composition comprising synthetic cardiolipin, synthetic lecithin, cholesterol and ethanol (see claim 7). Yabusaki teaches a composition wherein the concentration of cardiolipin is 0.03 %, concentration of cholesterol is 0.9 %, and concentration of lecithin is approximately 0.21 % (see claim 7, column 3, lines 10-25 and column 4, lines 61-65). Yabusaki does not teach tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine. However, these products have been known in the art and are commercially available from Avanti Polar Lipids Inc. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the commercially

Art Unit: 1645

available pure synthetic cardiolipin and lecithin powders having product numbers 710332 and 850457 to obtain the claimed composition.

20. Claims 13-17, 20 -21 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yabusaki, K. K. (US 4,738,932), and further in view of Avanti Polar Lipids product numbers 710332 and 850457.

The claims are drawn to a method for detecting anti-lipoidal antibodies in a human comprising combining a biological sample from the human with a composition comprising synthetic cardiolipin and synthetic lecithin and detecting an immunocomplex formed between an antibody in the biological sample and the composition.

Yabusaki, K. K. discloses a method for detecting anti-lipoidal antibodies in a human comprising combining a biological sample from the human with a composition comprising synthetic cardiolipin and synthetic lecithin and detecting an immunocomplex formed between an antibody in the biological sample and the composition (see claim 14 and column 2, lines 36-39). Yabusaki teaches that the immunocomplex is detected using agglutination test (see abstract). Yabusaki teaches a composition wherein the concentration of cardiolipin is 0.03 %, concentration of cholesterol is 0.9 %, and concentration of lecithin is approximately 0.21 % (see claim 7, column 3, lines 10-25 and column 4, lines 61-65). Yabusaki does not teach tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine.

However, these products have been known in the art and are commercially available from Avanti Polar Lipids Inc. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the commercially

Art Unit: 1645

available pure synthetic cardiolipin and lecithin powders having product numbers 710332 and 850457 to obtain the claimed method.

Conclusion

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnian-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Art Unit: 1645

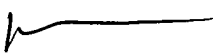

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

November 24, 2003



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER